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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/190,043	11/10/98	HOUCK J	47.653.2

HM12/0205

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EXAMINER	
BORIN, M	
ART UNIT	**PAPER NUMBER**
1631	19

DATE MAILED: 02/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.	Applicant(s)
09/190,043	Houck et al.
Examiner	**Group Art Unit**
Michael Borin	1631

THE PERIOD FOR RESPONSE: [check only a) or b)]

a) ☒ expires 5 months from the mailing date of the final rejection.

b) ☐ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on _____ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on Jan 19, 2001 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

☐ The proposed amendment(s):

☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.

☐ will not be entered because:

☐ they raise new issues that would require further consideration and/or search. (See note below).

☐ they raise the issue of new matter. (See note below).

☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

☐ Applicant's response has overcome the following rejection(s):

_____

☐ Newly proposed or amended claims _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:
SEE ATTACHED

☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: _____

Claims objected to: _____

Claims rejected: 1-3

☐ The proposed drawing correction filed on _____ ☐ has ☐ has not been approved by the Examiner.

☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). _____.

☐ Other

MICHAEL BORIN
PRIMARY EXAMINER
ART UNIT 1631

DETAILED ACTION

The main emphasis of discussion of the outstanding rejection, as presented in the response and Declarations, is discussion of Kermode reference and the issue of functional equivalence of different f-Met formyl peptides. It is noted that Gleisner et al., the primary reference used in the rejection, was given much less attention. The rejection states that Gleisner teaches that formyl Met peptides are capable of reducing effect of other pro-inflammatory agents in that they inhibit mast cell degranulation and histamine release evoked by the pro-inflammatory agents. The study concludes that the formyl Met peptides described in the reference as well as their structural analogs can be a useful addition to the existing antihistaminic drugs. Therefore, as it is well known that antihistamine drugs are used in the treatment of allergy reactions, it would be obvious to use formyl Met peptides in the treatment of allergy reactions.

The Response to Office action limits discussion of Gleisner reference to the brief statement that the reference does not teach use of the particular peptide used in the instant method. However, as was discussed in the previous Office action, the rejection is under 35 U.S.C. 103 and unobviousness cannot be established by attacking the references individually when the rejection is based on the combination of the references.

The Clagett Declaration turns to the reference at the end of discussion and seems to acknowledge that formyl Met peptides inhibit evoked degranulation and histaminic effect (paragraph

19)[1]. Then the Declaration briefly states that the peptide used in the instant invention seems to inhibit inflammation at earlier stages preceding mast cell degranulation. However, the claims are not drawn to a particular mechanism of action, but rather to an anti-allergy effect, and the latter use was made obvious in the Gleisner reference.

The Lipani Declaration does not address Gleisner reference at all.

Therefore, it does not seem that applicant provided substantial argument showing unobviousness of use of formyl Met peptides as anti-histamine agents.

As for the use of f-Met-Leu-Phe-Phe, it is noted that applicants contend that the peptide does not have pro-inflammatory effect by itself, which is different from the action of f-Met-Leu-Phe. However, Gleisner teaches that even the latter peptide f-Met-Leu-Phe (which, as argued by applicant, is a pro-inflammatory agent) inhibits mast cell degranulation and histamine release. Examiner has no reason to expect that f-Met-Leu-Phe-Phe which is demonstrated in Kermode as one of the most effective formyl Met peptides will not have effect similar to f-Met-Leu-Phe.

It is noted that the applicant compares statements of Gleisner about difference in the effects of f-Met-Leu-Phe on degranulation of mast cells and neutrophils (inhibition and activation, respectively) with observation of Kermode that f-Met peptides activate neutrophils. From this comparison applicant makes conclusion about variability of f-Met peptides as "functional equivalents". This conclusion is not clear as both references discuss that f-Met peptides are capable

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[1]It is noted that, immediately after this acknowledgment, in paragraph 21, the Declarant states that classification of formyl Met peptides as anti-histamine agents is not known.

of activating neutrophils. Even if applicant argues unobviousness of the use of f-Met-Leu-Phe-Phe due to some of its properties, the motivation in the prior art to combine references need not be identical to that of the applicant to establish obviousness.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

January 30, 2001

mlb

MICHAEL BORIN, PH.D.
PATENT EXAMINER